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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,866

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Kenneth J. Ruchala

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EXAMINER

KISH, JAMES M

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

12/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,866	<b>Applicant(s)</b> RUCHALA ET AL.	
	<b>Examiner</b> JAMES KISH	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/17/09</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 15, 2009 has been entered.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US Patent No. 5,117,829) – herein referred to as Miller – in view of Frohlich (US Patent Pub. No. 2002/0080915), and further in view of Robar et al. (US Patent Pub. No. 2001/0033682) – herein referred to as Robar. Miller discloses patient alignment systems and procedures for radiation treatment. Figure 8 illustrates a flowchart of the procedure. As can be seen in this figure, a patient is first exposed to an imaging procedure within a pod. The pod is used to repeatedly reposition the patient for the treatment process and, therefore, when the patient is in the pod he or she is considered to be in a treatment position. The patient is then transported within the pod to a treatment room and the table on which the patient and pod are attached is adjusted to settings determined by a treatment plan. Therefore, a treatment plan has already been created at this time. More images of the patient are acquired at this point in time. Corrections may be made, if they are required. If corrections are not required, treatment begins and adjustments may be made at any time once the treatment phase has begun. However, while it would be obvious to one of ordinary skill in the art that a treatment plan would include a dose distribution in radiation therapy, it is not explicitly stated within Miller that this is included within the treatment plan. Frohlich teaches a

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planning method and apparatus for radiotherapy treatment of a target volume in a body. The methods described by Frohlich "directly define the desired dose distribution instead of defining beam parameters. The desired dose distribution may be defined in different ways, e.g. by drawing on the two-dimensional (2D) CT slices (paragraph 6)." That paragraph also states that dose distribution may be determined via dose volume histograms (or DVH). Paragraph 11 describes the use of objective functions while paragraph 12 states that multiple treatment solutions are obtained. Paragraph 30-32 further describes multiple plan determination and benefits. Paragraph 25 teaches several imaging modalities that may be used to acquire images for the procedure. Therefore, it would be obvious to one of ordinary skill in the art that dose distributions may be determined via 2D images of a volume to be treated and it would be obvious to one of ordinary skill in the art to include a dose distribution plan in the treatment planning, as it is described and taught in Figure 8 of Miller, in order to later perform radiation therapy. Furthermore, the ability of Frohlich to create multiple treatment plans would improve the methods of Miller by removing the need for "gathering new CT scan data and formulating a new treatment plan (column 15, lines 66-67)," thereby saving time and money. However, neither Miller nor Frohlich teach that a three-dimensional image is used for volumetric dose calculations and used to compare with the treatment planning image.

Robar teaches a method for creating a volumetric data set representing a three-dimensional distribution, such as a dose distribution produced by a radiosurgery system (see Abstract). Upon creation of the three-dimensional dose distribution created by

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Robar, this image may be “spatially co-registered in treatment planning software for comparison with an intended dose distribution (see paragraph 45).” “Any deviations of the actual distribution from the intended dose distribution can thereby be identified before a radiosurgery treatment is delivered to a patient. The radiosurgery plan can be adjusted to correct these deviations (see paragraph 46).” It would be obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Robar to create a three-dimensional image of dose distribution for comparison with the three-dimensional images used in the treatment plan of Miller so that “Any deviations of the actual distribution from the intended dose distribution can thereby be identified before a radiosurgery treatment is delivered to a patient (see paragraph 46).”

Regarding new claims 28-31, the Examiner notes that these claims correspond to similar subject matter that was incorporated in now canceled claim 14. These features of the invention still read on the Miller reference as previously described and are rejected as such.

Regarding claims 33 and 35-39, these claims relate directly to original, now canceled claims 16-39, respectively. These claims are rejected over Miller as in the previous Office Actions.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/  
Supervisory Patent Examiner, Art  
Unit 3737

JMK